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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,649	01/26/2004	Haiyan Xu	MPI03-025P1RNM	8500

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EXAMINER	
HOWARD, ZACHARY C	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 11/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/764,649	XU ET AL.	
	Examiner	Art Unit	
	Zachary C Howard	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2 and 7-10, in so far as they are drawn to a method of identifying a nucleic acid molecule associated with a metabolic disorder, or to a method of identifying a subject having a metabolic disorder by detecting the presence of a nucleic acid molecule, classified in class 435, subclass 6, for example.

II. Claims 1, 3-7, and 11-13, in so far as they are drawn to a method of identifying a polypeptide associated with a metabolic disorder, or to a method of identifying a subject having a metabolic disorder by detecting the presence of a polypeptide, classified in class 435, subclass 7.2, for example.

III. Claims 14-15 and 22-23, in so far as they are drawn to a method for identifying a compound capable of modulating anaphylatoxin receptor nucleic acid expression, classified in class 435, subclass 6, for example.

IV. Claims 14-18 and 22-23, in so far as they are drawn to a method for identifying a compound capable of modulating anaphylatoxin receptor activity, classified in class 435, subclass 7.2, for example.

V. Claims 19-21, drawn to a method for modulating an anaphylotoxin receptor metabolic activity in a cell or tissue expressing the receptor, classified in class 514, subclass 1.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions I-V are directed to methods that are distinct both physically and functionally, and are not required one for the other. Inventions I and II require search and consideration of methods of screening biological samples to identify nucleic acid or polypeptides, which are not required by the other Inventions. Inventions III and IV require search and consideration of methods of screening compounds that modulate nucleic acid expression or polypeptide activity of an anaphylatoxin receptor, which is not required by the other Inventions. Invention V requires search and consideration of previously identified molecules that can modulate an anaphylatoxin receptor mediated activity, which is not required by the identified molecules.

Inventions I and II are both methods of identification, but they are independent and distinct because Invention I is a method of using a polynucleotide and Invention II is a method of using a polypeptide. Inventions III and IV are independent and distinct for the same reason. The polynucleotides and polypeptides are independent and distinct, each from each other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged.

The polynucleotide and polypeptides are patentably distinct for the following reasons: polypeptides (composed of amino acids) and polynucleotides (composed of purines and pyrimidines) are structurally distinct molecules; any relationship between

them depends upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Furthermore, the search of the polynucleotides and polypeptides together would impose a serious search burden. The two inventions have a separate status in the art as shown by their different classifications. In cases such as this where descriptive sequence information is provided, the protein and nucleic acid sequences are searched in databases that are not coextensive. In addition, the technical literature search is not coextensive. A protein may be described in the literature prior to the concomitant isolation and expression of the nucleic acid sequence. Similarly, there may be "classical" genetics papers that describe the gene but not the polypeptide. Furthermore, a search of the nucleic acid sequences would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide.

Because the polynucleotides and polypeptides are independent and distinct, the methods of using each are also independent and distinct.

Because these inventions are distinct for the reasons given above and the search required for each of the Groups is not required for the other Groups, restriction for examination purposes as indicated is proper.

Further Restriction Within Group I or III

If Group I is elected, further restriction within the elected group is required, as follows to one of the following molecules: SEQ ID NO: 1 (C3aR polynucleotide), SEQ ID NO: 3 (C5aR polynucleotide), SEQ ID NO: 5 (HAP polynucleotide), SEQ ID NO: 7 (OPN polynucleotide), or SEQ ID NO: 17 (MCP-1 polynucleotide).

If Group III is elected, further restriction within the elected group is required, as follows to one of the following molecules: SEQ ID NO: 1 (C3aR polynucleotide) or SEQ ID NO: 3 (C5aR polynucleotide).

Although classifications for each of the nucleic acids are overlapping, each represents a patentably distinct product, having different sequences and structures and requiring separate sequence searches. Therefore methods of using the polynucleotides are also patentably distinct.

Applicants are advised that this is not a species election.

Further Restriction within Group II, IV, or V

If Group II is elected, further restriction within the elected group is required, as follows to one of the following molecules:SEQ ID NO: 2 (C3aR polypeptide), SEQ ID NO: 4 (C5aR polypeptide), SEQ ID NO: 6 (HAP polypeptide), SEQ ID NO: 8 (OPN polypeptide), or SEQ ID NO: 18 (MCP-1 polypeptide).

If Group IV or V is elected, further restriction within the elected group is required, as follows to one of the following molecules:SEQ ID NO: 2 (C3aR polypeptide) or SEQ ID NO: 4 (C5aR polypeptide).

Although classifications for each of the polypeptides are overlapping, each represents a patentably distinct product, having different sequences and structures and requiring separate sequence searches. Therefore methods of using the polypeptides are also patentably distinct.

Applicants are advised that this is not a species election.

Further Restrictions within Group III, IV or V

If Group III, IV or V is elected, further restriction within the elected group is required, as follows to one of the following activities: interaction with a non-anaphylatoxin receptor molecule, activation of an anaphylotoxin receptor-dependent signal transduction pathway, modulation of C3a or C5a gene expression or protein activity, modulation of insulin signaling, modulation of glucose metabolism, or modulation of insulin metabolism.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for Inventions that are directed to <u>different</u> methods,

restriction is deemed to be proper because these method steps appear to constitute patentably distinct inventions for the following reasons: these method steps are directed to activities that are distinct both physically and functionally, and are not required one for the other. Each requires search and consideration of molecules, intracellular signaling pathways, or metabolic pathways that are not required for the other activities. Bcause these inventions are distinct and the search required for each activity is not required for the other activity, restriction for examination purposes as indicated is proper.

Applicants are advised that this is not a species election.

Further restriction within Group V

If Group V is elected, further restriction within the elected group is also required, as follows, to one of the following: a small molecule anaphylatoxin receptor antagonist, a small molecule anaphylatoxin receptor inverse antagonist, an anti-anaphylatoxin receptor antibody, an antisense anaphylatoxin receptor molecule, and anaphylatoxin receptor ribozyme.

These molecules represent patentably distinct products, having different structures and/or sequences, and different classifications. Therefore, methods of using these molecules are also patentably distinct. Because these inventions are distinct and the search required for each molecule is not required for the other molecules, restriction for examination purposes as indicated is proper.

Applicants are advised that this is not a species election.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Eileen B. O'Hara

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EILEEN B. O'HARA
PATENT EXAMINER